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10/551,990	03/06/2006	Kazutomo Inoue	2005_1502A	6411

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,990	INOUE ET AL.	
	Examiner	Art Unit	
	Tiffany M. Gough	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/22/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7 and 9-18* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 02/22/2007 has been received and entered into the case. Claims 1,3-7,9-18 are pending, claims 2 and 8 have been cancelled by applicant, claims 10-16 have been withdrawn. Claims 1,3-7,9,17,18 have been considered on the merits. All arguments and amendments have been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-7, 9,17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aung et al (Transplantation Proceedings, vol. 27, no. 1, 1995), Inuoe et al (Pancreas, 1992) and Mitsuo et al (Transplantation Proceedings, 1992) in view of Kanazawa et al (Cell Transplantation, 1999) and Inui et al (Pancreas, 2001).

Applicant claims a cellular preparation comprising pancreatic islet cells in polyvinyl alcohol mixed with a cell preservative such as Euro–Collins, UW, or Cell Banker solutions wherein the surface of the cells is coated with an extracellular matrix, and growth factor, which is implanted subcutaneously, intraabdominally, or intramuscularly. The cellular preparation has a tubular, rod, plate, sheet or bead-like shape. Applicant also claims a pharmaceutical composition comprising the cellular preparation comprising pancreatic islet cells in polyvinyl alcohol mixed with a cell preservative such as Euro–Collins, UW, or Cell Banker solutions wherein the surface of the cells is coated with an extracellular matrix.

Aung teaches a pancreatic islet cell preparation in RPMI medium, i.e. a cell preservative, mixed with collagen, i.e., an extracellular matrix, and fetal bovine serum (FBS), i.e. a growth factor, in a mesh reinforced polyvinyl alcohol tube (Materials and Methods section p.619).

Inoue et al (Pancreas, 1992) teach a cellular preparation comprising pancreatic islet cells in polyvinyl alcohol (PVA) transplanted into the peritoneal cavity of rats. The polyvinyl alcohol membrane allows the passage of insulin, glucose, and nutrients to patients in which the cell preparation had been transplanted into (see summary). The

membrane is tubular and rod-like in shape (see materials and methods section). The PVA membrane is a promising membrane satisfying the requirements for a bioartificial pancreas: it has good permeability of insulin, glucose and nutrients, but not for immunological macromolecules and insignificant encapsulation around the hydrogel membrane after implantation (see Discussion section, 2nd paragraph). Further, they disclose that the entrapment of pancreatic islet cells in a polyvinyl alcohol membrane is more effective in inducing a sustained decrease in nonfasting blood glucose levels in diabetic rats without the use of immunosuppressive therapy than the transplantation of free islets, thus the PVA membrane could provide total protection of islet cells from the graft rejection and autoimmune destruction while eliminating the need for immunosuppression (see p.567, 1st full paragraph).

Mitsuo et al (Transplantation Proceedings, 1992) teach pancreatic islet cells in a PVA tube membrane which is transplanted intraabdominally into a recipient (see p. 2939, Islet isolation and MRPT implantation section).

Neither Aung, Inoue or Mitsuo teach the claimed cell preservative.

Kanazawa et al (Cell Transplantation, 1999) teach islet cells in a cell preservative, specifically UW solution and Euro-Collins solution. They disclose UW solution as being a successful islet cell preservative when the cells are used for transplantation and is especially useful in preserving the insulin secretion properties of the islet cells after cold storage (see abstract, introduction, results section, and p.388 5th paragraph).

Inui et al (Pancreas, 2001) teach that clinical pancreatic islet transplantation requires cold storage of islets for several hours, thus there is a need for optimal storing/preservation of the cells. They disclose UW solution is the best solution for such purposes. Further, they teach pancreatic islet cells in RPMI medium with FBS, i.e. a growth factor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a cell preservative such as those taught by Kanazawa and Inui in a cellular preparation such as those disclosed by Aung, Inuoe and Mitsuo because the cell preservatives are known in the art as being successful in storing and preserving islet cells and especially successful in preserving the insulin secreting properties. Thus, improving the stability of transplantable islet cells would be obvious to one or ordinary skill in the art.

One of ordinary skill in the art would have been motivated to used a cell preservative such as those taught by Kanazawa and Inui in a cellular preparation such as those disclosed by Aung, Inuoe and Mitsuo because the cell preservatives are known in the art as being successful in storing and preserving islet cells and especially successful in preserving the insulin secreting properties. Thus, improving the stability of transplantable islet cells would be motivation to use a cell preservative such as those claimed by applicant and taught by Kanazawa and Inui. Further, one would have expected success in using such preservatives because they are known in the art to be successful in preserving islet cells used for transplantation.

Claims 1,3-7, 9,17,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al (Transplantation Proceedings, vol. 27, no. 6, December 1995) in view of Aung et al (Transplantation Proceedings, vol. 27, no. 1, 1995), Kanazawa et al (Cell Transplantation, 1999) and Inui et al (Pancreas, 2001).

Applicant claims a cellular preparation comprising pancreatic islet cells in polyvinyl alcohol mixed with a cell preservative such as Euro–Collins, UW, or Cell Banker solutions wherein the surface of the cells is coated with an extracellular matrix, and growth factor, which is implanted subcutaneously, intraabdominally, or intramuscularly. The cellular preparation has a tubular, rod, plate, sheet or bead-like shape. Applicant also claims a pharmaceutical composition comprising the cellular preparation comprising pancreatic islet cells in polyvinyl alcohol mixed with a cell preservative such as Euro–Collins, UW, or Cell Banker solutions wherein the surface of the cells is coated with an extracellular matrix.

Hayashi et al teach a MIN6 B-cell line, i.e. transformed cells cultured in DMEM, i.e. a cell preservative with fetal bovine serum (FBS), i.e. a growth factor, in a mesh reinforced polyvinyl alcohol tube which is transplanted into the peritoneal cavity of rats (see p.3358 Materials and Methods section continued to p.3359, 1st paragraph).

Hayashi does not teach the addition of an extracellular matrix, i.e. collagen or the claimed cell preservative.

Aung teaches a pancreatic islet cell preparation in RPMI medium, i.e. a cell preservative, mixed with collagen, i.e., an extracellular matrix, and fetal bovine serum

(FBS), i.e. a growth factor, in a mesh reinforced polyvinyl alcohol tube (Materials and Methods section p.619). They teach collagen to be effective in prevention of islet aggregation on the PVA membrane (see p.620 Discussion section, 3rd paragraph).

Kanazawa et al (Cell Transplantation, 1999) teach islet cells in a cell preservative, specifically UW solution and Euro-Collins solution. They disclose UW solution as being a successful islet cell preservative when the cells are used for transplantation and is especially useful in preserving the insulin secretion properties of the islet cells after cold storage (see abstract, introduction, results section, and p.388 5th paragraph).

Inui et al (Pancreas, 2001) teach that clinical pancreatic islet transplantation requires cold storage of islets for several hours, thus there is a need for optimal storing/preservation of the cells. They disclose UW solution is the best solution for such purposes. Further, they teach pancreatic islet cells in RPMI medium with FBS, i.e. a growth factor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a cell preservative such as those taught by Kanazawa and Inui in a cellular preparation such as those disclosed by Aung and Hayashi because the cell preservatives are known in the art as being successful in storing and preserving islet cells and especially successful in preserving the insulin secreting properties. Thus, improving the stability of transplantable islet cells would be obvious to one or ordinary skill in the art.

One of ordinary skill in the art would have been motivated to used a cell preservative such as those taught by Kanazawa and Inui in a cellular preparation such as those disclosed by Aung and Hayashi because the cell preservatives are known in the art as being successful in storing and preserving islet cells and especially successful in preserving the insulin secreting properties. Thus, improving the stability of transplantable islet cells would be motivation to use a cell preservative such as those claimed by applicant and taught by Kanazawa and Inui. Further, one would have expected success in using such preservatives because they are known in the art to be successful in preserving islet cells used for transplantation.

Response to Arguments

Applicant's arguments filed 2/22/2007 have been fully considered but they are not persuasive. In light of the new rejections, the claims are rejected. Applicant argues that the art does not teach the cell preservatives, PVA membrane and extracellular matrix of the invention. New rejections have been applied as necessitated by amendment, which teach/suggest the limitations of claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tiffany Gough

/Ruth A Davis/
Primary Examiner, AU 1651